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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/889,203

03/13/2002

Tracey Brown

HACK:011US

8511

7590

06/30/2005

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/889,203	BROWN, TRACEY	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*Handwritten initials/signature*

### DETAILED ACTION

Examiner acknowledges receipt of request for continued examination filed under 37 CFR 1.114, request for extension of time, amendment and remarks filed 03/14/05. Claims 1-9 are pending.

#### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/14/05 has been entered.

### NEW MATTER

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of hyaluronic acid having molecular weight of greater than or equal to 750,000 Daltons is new matter. Although applicants in the amendment that inserted the molecular indicated that there is support for the amendment in the specification as originally

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filed, the specific page and lines in the specification providing the support was not stated and Examiner does not find support for the amendment.

4. Upon removal of the new matter from the claims the previous rejection would remain.

***Claim Rejections - 35 USC § 102***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 6, 7 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Turley et al. (US 6,475,795 B1).

7. Turley discloses pharmaceutical composition that comprises anti-sense nucleic acid bound to hyaluronic acid for treating diseases or conditions treatable using gene therapy (column 6, line 60 to column 7 line 10; column 2, line 62 to column 3 line 7 and claims 1-8). Turley specifically discloses that hyaluronan having a molecular weight of between 150,000 Daltons and 750,000 Daltons is preferred (column 7, lines 11-15 and 33; column 9, lines 37-40; claims 2 and 3). In column 7, line 64, hyaluronan having molecular weight of between 500,000 and 800,000 is used and larger molecular weight hyaluronan can be used in Turley except for hyaluronan having molecular weight exceeding 1,000,000 because at greater than 1,000,000, the hyaluronan self aggregates (column 10, lines 7-14). On the basis that Turley discloses larger molecular weight hyaluronan up to 1,000,000 but not exceeding, 1,000,000, there is then a disclosure for use of hyaluronan having molecular weight of greater than 750,000 in the formulation of Turley. Therefore, Turley meets the limitations of the designated claims. The previous rejection will remain when the new matter is removed.

*Claim Rejections - 35 USC § 103*

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk et al. (US 5,985,850).

Falk discloses injectable formulations comprising anti-cancer agent or chemotherapeutic agent and hyaluronic acid (column 10, lines 8-59). The preferred molecular weight for the hyaluronan is less than 750,000 Daltons (claims 142, 83, 84 and 92). There is no demonstration in applicant's specification that a molecular weight of greater than or equal to 750,000 Dalton provides unusual and unexpected results. A molecular weight of greater than or equal to 750,000 Daltons is not inventive over the disclosure in the prior art of a molecular weight of less than 750,000. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject a composition comprising hyaluronic acid and anti-cancer agent to a subject in need thereof. One having ordinary skill in the art would have been motivated to use hyaluronic acid having the appropriate molecular weight that would provide the desired therapeutic effect and viscosity of the composition.

10. Claims 1-9 are rejected under in the alternative, under 35 U.S.C. 103(a) as obvious over Turley et al. (US 6,475,795 B1).

Turley is described above. There is a disclosure for composition comprising hyaluronic acid having molecular weight of 500,000 to 800,000 Daltons and a composition that may have hyaluronan having preferred molecular weight of between 15,000 and 750,000 Daltons. Since molecular weight of between 150,000 and 750,000 Daltons is less than 750,000 Daltons, Turley

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renders the claims obvious because a molecular weight of greater than 750,000 Daltons is not inventive over the prior art. There is no demonstration in applicant's specification that a molecular weight of greater than or equal to 750,000 Dalton provides unusual and unexpected results. A molecular weight of greater than or equal to 750,000 Daltons is not inventive over the disclosure in the prior art of a molecular weight of between 150,000 and 750,000 Daltons.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject a composition comprising hyaluronic acid and anti-sense agent to a subject in need thereof. One having ordinary skill in the art would have been motivated to use hyaluronic acid having the appropriate molecular weight that would provide the desired therapeutic effect and viscosity of the composition and where the molecular weight does not exceed 1,000,000 in order to avoid aggregation of the hyaluronan.

The prior rejection is effective when the new matter is removed from the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in black ink, appearing to read 'Blessing Fubara', is written over the printed name.